No. 24-50180

# In the United States Court of Appeals for the Fifth Circuit

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCATION, on behalf of itself and its members; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members,
*Plaintiffs-Appellants*,

*v.*

XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES,
*Defendants-Appellees*.

On Appeal from the U.S. District Court for the Western District of Texas
No. 1:23-cv-707 (Hon. David Alan Ezra)

## APPELLANTS' UNOPPOSED MOTION TO EXPEDITE BRIEFING AND ARGUMENT


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## CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 27.4 and 28.2.1, undersigned counsel certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of these appeals. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. **Plaintiff-Appellant the National Infusion Center Association (NICA).** The following attorneys have represented NICA in this case:

> Tim Cleveland, Austin Krist, Ibituroko-Emi Lawson, McKenzie Edwards and Gerard Bifulco of Cleveland Krist LLC.

2. **Plaintiff-Appellant the Global Colon Cancer Association (GCCA).** GCCA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented GCCA in this case:

> Michael Kolber and Megan Thibert-Ind of Manatt, Phelps & Phillips LLP.

3. **Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America (PhRMA).** PhRMA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented PhRMA in this case:

Jeffrey Handwerker, John Elwood, Allon Kedem, William Perdue, and Allissa Pollard of Arnold & Porter Kaye Scholer LLP.

4. **Defendant-Appellees Xavier Becerra, the U.S. Department of Health and Human Services, Chiquita Brooks-Lasure, and the Centers for Medicare and Medicaid Services.** The following attorneys have represented the Government in this case:

Brian M. Boynton, Jaime Esparza, Michelle R. Bennett, Stephen M. Pezzi, Christine L. Coogle, and Alexander V. Sverdlov.

Dated: March 22, 2024

/s/ *John Elwood*
John Elwood

*Counsel for Appellant Pharmaceutical Research and Manufacturers of America*

Pursuant to Fed. R. App. P. 2 and 5th Cir. R. 27.5 and 34.5, Plaintiffs-Appellants the National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully request that the Court expedite this appeal of the district court's order dismissing Plaintiffs' claims for lack of subject-matter jurisdiction and improper venue. Defendants-Appellees Xavier Becerra, the U.S. Department of Health and Human Services (HHS), Chiquita Brooks-LaSure, and the Centers for Medicare and Medicaid Services (collectively, the Government) does not oppose the proposed schedule.

## INTRODUCTION

This lawsuit challenges an unconstitutional statute that already inflicts massive harm on Plaintiffs. Expedited briefing and argument is necessary to correct course after the district court's erroneous refusal to exercise jurisdiction. The Government will not be prejudiced by expedition; indeed, the Government indicated below that it "share[s] [Plaintiffs'] desire to get this all resolved as soon as we can."

In 2022, Congress passed the Inflation Reduction Act (IRA), ending decades of a market-based system for reimbursing prescription drugs in favor

of government-dictated price controls. The IRA mandates sham "negotiations" whereby the government sets a "maximum fair price" for certain selected drugs—some of the most innovative and widely used. Pharmaceutical manufacturers must either accept these government-imposed prices or face draconian penalties. Left in place, this new regime will dramatically slow innovation, reduce the availability of new medicines, and undermine public health, causing grave harm to patients, pharmaceutical manufacturers, and healthcare providers.

In fact, the IRA has *already* begun to harm Plaintiffs. The Act inflicts quintessential procedural injuries on Plaintiffs, depriving them of constitutionally required due process, impermissibly delegating legislative power to HHS, and coercing compliance via excessive fines. Indeed, despite having foreclosed input at key stages and purported to preclude challenges to agency decisions implementing the program, the Secretary announced the first ten selected drugs on August 29, 2023. PhRMA's members manufacture eight of them and thus have been forced into the first round of "negotiations," which is scheduled to run until August 1, 2024, with HHS publishing the maximum "fair" price the following month. The first list includes drugs administered and dispensed by members of Plaintiff NICA, limiting their

ability to raise funding. As a result, every day, manufacturers and providers are being subjected to unconstitutional agency proceedings. And every day, they are forced to make major business decisions in response that have significant consequences for patients and the public.

In June 2023, Plaintiffs challenged the IRA's constitutionality in the Western District of Texas.[1] Given the IRA's impending deadlines, the parties agreed to an expedited schedule in which they would proceed directly to cross-motions for summary judgment. Shortly after Plaintiffs filed their motion for summary judgment, however, the Government reneged on the agreement, requested that the district court vacate the joint scheduling order, and moved to dismiss NICA's claims for lack of subject-matter jurisdiction. The district court ultimately granted the Government's motion. With NICA dismissed, the court concluded that venue was no longer proper as to GCCA and PhRMA.

[1] Plaintiffs' suit is one of many challenging the IRA's constitutionality. *See Merck & Co. v. Becerra*, No. 1:23-01615 (D.D.C.); *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156 (S.D. Ohio); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-03335 (D.N.J.); *Astellas Pharma US, Inc. v. HHS*, No. 1:23-cv-4578 (N.D. Ill.); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn.); *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:23-cv-00931 (D. Del.); *Novartis Pharmaceuticals Corp. v. Becerra*, No. 2:23-cv-14221 (D.N.J.); *Novo Nordisk, Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J.).

Good cause exists to expedite this appeal. The constitutional harms inflicted on Plaintiffs are irreparable. And as more of the IRA's statutory deadlines are triggered, it will become increasingly difficult to unwind the Act's other harmful effects. Because Plaintiffs' proposed timeline will not prejudice the Government, and the Government does not oppose the proposed schedule, this Court should grant Plaintiffs' motion.

## BACKGROUND

### A. The Inflation Reduction Act

The IRA upends Medicare's traditional market-based system. Although the statute directs HHS to establish a "Drug Price *Negotiation* Program," 42 U.S.C. § 1320f(a) (emphasis added), the statute in fact empowers HHS to set drug prices by administrative *fiat*.

#### *HHS Ranks and Selects "Negotiation-Eligible Drugs"*

The IRA directs HHS to rank "negotiation-eligible drugs" based on Medicare's total annual expenditures. *Id.* § 1320f–1(b)(1)(A). Drugs with the highest total expenditures are ranked highest. *Id.* The IRA directs HHS to select ten Part D drugs in 2023, with government-imposed "maximum fair prices" taking effect in 2026; then an increasing number of the highest-ranked drugs will be selected annually. *Id.* § 1320f–1(a)(1)–(4). Part B drugs will be

added beginning in 2026, with maximum prices taking effect in 2028. *Id.* § 1320f–1(a)(1), (3). The first ten drugs were selected on August 29, 2023. *See* HHS Selects the First Drugs for Medicare Drug Price Negotiation, bit.ly/4367QNC.

***HHS Sets "Maximum Fair Prices" Through Sham "Negotiations"***

Once drugs are selected, the IRA directs HHS to "enter into agreements with manufacturers" to "negotiate to determine (and … agree to) a maximum fair price." *Id.* §§ 1320f–2(a), (a)(1). Manufacturers of drugs on the first list of selected drugs were required to enter into these "agreements" by October 1, 2023. *Id.* §§ 1320f(d)(2)(A), 1320f–2(a). The ensuing "negotiations" must conclude by August 1, 2024. *Id.* §§ 1320f(d)(5), 1320f–3(b)(2)(E).

While the IRA's "negotiation" process includes a sham offer/counteroffer framework, *id.* § 1320f–3(b)(2)(C)–(D), that is where any resemblance to ordinary commercial negotiations ends. The IRA places a "ceiling" on how *high* a price HHS can offer. *Id.* § 1320f–3(c). But with one minor exception, the statute does not limit how *low* a price HHS can demand, *id.* § 1320f–3(b)(2)(F), and it commands HHS to "aim[] to achieve the lowest maximum fair price," *id.* § 1320f–3(b)(1). While HHS must "consider" specified

"factors," the IRA sets no criteria for how HHS must weigh them. *Id.* § 1320f–3(e).

Once HHS has imposed a price, the manufacturer must provide "access to such price to" individuals, pharmacies, providers, and other entities participating in Medicare. *Id.* § 1320f–2(a)(1). Manufacturers that fail to do so must pay a per-unit penalty of *ten times* the difference between the price charged and the HHS-imposed price. *Id.* § 1320f–6(b).

***Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"***

The linchpin of the IRA's forced-negotiation scheme is a so-called "excise tax"—a steep, escalating penalty for every day the manufacturer has not, by the deadline, (1) entered into an "agreement" to "negotiate" a price, or (2) "agreed" to the price that HHS imposes. 26 U.S.C. § 5000D(b). While labeled an "excise tax," it is intended to coerce rather than to raise revenue.

The size of this "tax" is staggering. By the terms of the statute, the tax applies to *all* U.S. sales of the drug, not just Medicare sales. *See id.* The tax is calculated based on a high "applicable percentage" of the drug's total cost (price plus tax) that increases for each quarter of noncompliance. *Id.* § 5000D(d). Per the Congressional Research Service, "[t]he excise tax rate" thus "range[s] from 185.71% to 1,900% of the selected drug's price depending

on the duration of noncompliance." CRS, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 (Aug. 10, 2022).

The excise-tax penalty will not be "[s]uspen[ded]," 26 U.S.C. § 5000D(c), unless the manufacturer withdraws *all* of its drugs from Medicare Part D, Medicare Part B, *and* Medicaid. *See id.*; 42 U.S.C. § 1396r-8(a)(1). That would leave Medicare and Medicaid participants without access to badly needed medications. ECF 1 ¶¶ 118, 126.[2]

### B. The Proceedings Below

Plaintiffs filed their Complaint on June 21, 2023. ECF 1. Plaintiffs asserted three claims, arguing that the IRA violates (1) the separation of powers and the nondelegation doctrine, (2) the Eighth Amendment's Excessive Fines Clause, and (3) the Fifth Amendment's Due Process Clause.

In July, the parties conferred regarding the case schedule. ECF 41 at 1–2. Plaintiffs explained the need to expedite the case given the IRA's impending deadlines. *Id.* To avoid the need to seek a preliminary injunction or other extraordinary relief, Plaintiffs suggested that the parties move directly to cross-motions for summary judgment. *Id.* at 2. The Government agreed and

[2] All ECF citations are to the docket below, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-CV-707 (W.D. Tex.).

affirmed that it "share[d] [Plaintiffs'] desire to get this all resolved as soon as we can." *Id.*

The parties jointly proposed an expedited schedule, ECF 33, which the district court entered, ECF 34. On August 10, 2023, Plaintiffs moved for summary judgment, just seven weeks after filing the Complaint. ECF 35. Based on the parties' agreement, the Government's cross-motion for summary judgment was due on September 29, 2023, with briefing set to be completed by November 17, 2023. ECF 34.

But rather than cross-move for summary judgment, the Government reneged on the parties' agreement, successfully moved to vacate the joint scheduling order over Plaintiffs' opposition, and moved to dismiss. *See* ECF 39–40, 45. The Government argued that NICA lacks standing because it has not suffered a cognizable injury and, regardless, did not exhaust its administrative remedies. *See* ECF 39 at 1–3. And because NICA is the only Plaintiff that "resides" in the Western District of Texas for venue purposes, the Government argued that the district court should dismiss the case for lack of venue. *Id.*

In a 13-page decision, the district court dismissed the case for lack of subject-matter jurisdiction and improper venue. ECF 53 at 12–13. The court

ruled solely on the ground that NICA failed to present its claim to the relevant agency and exhaust purported administrative remedies. *Id.* at 6–12. The court held that NICA's claims "arise under the Medicare Act and [that] Section 405(h) channeling [thus] applies." *Id.* at 10. Because NICA did not submit its constitutional challenges to HHS before filing suit, the court concluded that it lacked subject-matter jurisdiction over NICA. *Id.* at 10–12. Without NICA, the court held that venue was improper as to GCCA and PhRMA. *Id.* at 12–13.

## ARGUMENT

This Court may expedite an appeal, including entering an abbreviated briefing scheduling and advancing the case for hearing, for "good cause." 5th Cir. R. 27.5 and 34.5. Good cause exists here because the IRA is causing ongoing, irreparable harm to Plaintiffs; the dispute presents purely legal questions; and the Government does not oppose and cannot show prejudice from a modestly accelerated timeline.

### I. Both Sides Have an Interest in Resolving Challenges to the IRA's Constitutionality Expeditiously

The district court's jurisdictional dismissal here threatens to add substantial delay to Plaintiffs' challenge to the IRA. Meanwhile, "negotiations" have already begun, and manufacturers are already being compelled to participate in an unconstitutional process. Providers likewise are

seeing their interests harmed by that same unconstitutional process, and are already facing additional barriers to raising capital as a result. The Government, in turn, continues to enforce a statutory regime the constitutionality of which remains undecided by any appellate court. Because neither side benefits from the IRA's legal limbo, this Court should expedite briefing and argument.

Every day the IRA's drug pricing regime remains in effect it inflicts serious procedural harms on Plaintiffs. Being "deprived of 'a procedural right to protect [one's] concrete interests'" is an immediate injury. *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (citation omitted). Likewise, "subjection to an unconstitutionally structured decisionmaking process"—such as "an agency … wielding authority unconstitutionally"—is an injury "irrespective of [the] outcome." *Axon Enter. v. FTC*, 598 U.S. 175, 189, 192 (2023). "The loss is not merely the subsequent deprivation, but the right not to suffer a deprivation without proper process." *Bertulli v. Indep. Ass'n of Cont'l Pilots*, 242 F.3d 290, 295 (5th Cir. 2001). It is "being compelled to participate in an invalid administrative process" in the first place. *Texas v. United States*, 497 F.3d 491, 496-97 (5th Cir. 2007).

The IRA is already subjecting manufacturers and providers to an unconstitutional agency procedure, inflicting constitutional harm now. First, the IRA fails to provide Plaintiffs even rudimentary due process: "The Act . . . fail[s] to provide manufacturers, providers, and patients with any opportunity to weigh in on key determinations by HHS on the 'front' end (*i.e.*, before decisions are made) and by foreclosing judicial and administrative review of those determinations on the 'back' end (*i.e.*, after decisions have been made)." ECF 1 ¶ 146. Second, the IRA operates via an unconstitutional delegation of legislative power to HHS. Congress unconstitutionally "delegated unfettered discretion to HHS to set prices," which is "a wholly legislative function." *Id.* ¶¶ 75, 79. Finally, the entire "negotiation" process is enforced through the threat of unconstitutionally excessive fines.

The IRA's statutory deadlines continue to roll out at a steady clip. In August 2023, HHS selected the first ten drugs for "negotiation," including drugs that PhRMA's members manufacture and NICA's members dispense and administer.[3] CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (August 2023),

[3] The first list of selected drugs includes Stelara®, which several NICA members dispense and administer, and for which they are reimbursed under Medicare. ECF 47 at 13–14.

https://bit.ly/3Ewqkvg. Manufacturers of selected drugs were required to enter "agreements" to "negotiate" with HHS by October 1, 2023. Those negotiations are ongoing and must be completed by August 1, 2024, with publication of the so-called "maximum fair price" for selected drugs a month later. Given their lack of input and opportunity to challenge the agency's determinations, Plaintiffs will continue to suffer the "here-and-now injury," *Axon Enter.*, 598 U.S. at 192, of "being compelled to participate in [this] invalid administrative process," *Texas*, 497 F.3d at 496–97. Every day that goes by without a merits ruling compounds that procedural harm.

Plaintiffs are already experiencing monetary harms as well. As long as the sham "negotiations" continue, manufacturers and providers must make significant, long-term business decisions to account for their effects. For example, manufacturers must decide on research and development investments years in advance, and they cannot make informed decisions while awaiting a ruling on the constitutionality of the IRA's drug-pricing regime. And the IRA "is already impacting the ability of NICA's members," some of whom "are currently courting private equity investments," "to raise debt and equity funding." ECF 47-2 ¶ 20. Even if Plaintiffs ultimately prevail in this lawsuit, they will not be able to recover these costs from the Government. *See*

*Wages & White Lion Invs., L.L.C. v. U.S. Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) ("Indeed, complying with an agency order later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs . . . because federal agencies generally enjoy sovereign immunity for any monetary damages.").

Prompt resolution of this case also will benefit the Government. The Government is defending numerous lawsuits challenging the drug-pricing regime, all of which consume significant resources. The Government also continues to commit substantial resources to implementing the drug-pricing program, which will be wasted should Plaintiffs prevail.

## II. The Government Cannot Show Prejudice From a Modestly Accelerated Timeline Involving Discrete Legal Questions

Plaintiffs' proposed briefing schedule will not prejudice the Government, both because this appeal presents purely legal questions, and because the Government has previously expressed its desire to resolve this dispute quickly.

In its thirteen-page order, the district court decided only whether NICA's claims arose under the Medicare Act, and, if so, whether channeling those claims through the agency would have foreclosed judicial review. *See* ECF 53. The Government briefed that issue in just four-and-a-half pages in

the district court. *See* ECF 39 at 12–14. And although the court did not reach the issue of Article III standing, that issue turns on the allegations in the Complaint and two short declarations from Plaintiffs. Given the discrete legal questions this appeal presents, the proposed schedule below provides the Government ample time to address Plaintiffs' arguments.

Further, the Government agreed to an expedited briefing schedule in the district court, skipping the answer stage and discovery altogether and proceeding directly to summary judgment. ECF 33. The Government confirmed then that it "share[d] [Plaintiffs'] desire to get this all resolved as soon as we can." ECF 41 at 2. The Government has not indicated that it would suffer prejudice as a result of Plaintiffs' proposed briefing schedule. And the public interest is served by a speedy ruling on the constitutionality of a process that will consume substantial public resources.

## CONCLUSION AND PROPOSED SCHEDULE

For all these reasons, Plaintiffs respectfully request that the Court expedite the briefing schedule and oral argument in this case. Plaintiffs propose the following schedule:

**Plaintiffs' Opening Brief:** 28 days from the Court's order

**The Government's Opposition Brief:** 35 days from Plaintiffs' brief

**Plaintiffs' Reply Brief:** 21 days after the Government's opposition brief

**Oral argument:** June or July 2024, or the Court's earliest convenience

Dated: March 22, 2024

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2024, the foregoing document was electronically filed with the Court via the appellate CM/ECF system, and that copies were served on counsel of record by operation of the CM/ECF system on the same date.

Dated: March 22, 2024

/s/ *John Elwood*
John Elwood

*Counsel for Appellant*
*Pharmaceutical Research and*
*Manufacturers of America*

## CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because the motion contains 3,059 words excluding the parts of the motion exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2. This motion complies with the typeface and type style requirements of Fifth Circuit Rule 32.1 and Fed. R. App. P. 32(a)(5) and 32(a)(6), respectively, because this motion has been prepared in a proportionately spaced typeface using Microsoft Word in Century Expanded BT 14-point font.

Dated: March 22, 2024

/s/ *John Elwood*
John Elwood

*Counsel for Appellant*
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